REMARKS/ ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

Disposition of the Claims

Claims 46, 48, 51, 53-58, and 60 are pending in this application.

Rejections under 35 U.S.C. §102

A. Claims 46, 48, 51-58, and 60 stand rejected under 35 U.S.C. §102(b) as being anticipated by Chen et al. (U.S. Patent No. 5,558,879). Claim 52 has been cancelled. Accordingly, rejection of claim 52 is moot. Reconsideration of the rejection of claims 46, 48, 51, 53-58, and 60 is respectfully requested.

Claim 46 recites a dosage form comprising a formulation comprising a therapeutic agent. A first membrane is in contact with the formulation. The first membrane consists essentially of a hydrophobic substance and a hydrophilic substance exhibiting an aqueous solubility that is responsive to osmotic pressure and/or ionic strength of the formulation. A second membrane is positioned over an outside surface of the first membrane. The second membrane is a semipermeable membrane that maintains its physical and chemical integrity as the dosage form dispenses the therapeutic agent. By reciting that the second membrane is a semipermeable membrane that maintains its physical and chemical integrity as the dosage form dispenses the therapeutic agent, it is implicit that the second membrane is essentially water-insoluble.

In order for Chen et al. to anticipate claim 46, Chen et al. would have to disclose each and every limitation recited in claim 46. Chen et al. disclose a tablet comprising a compressed core and a dual layer coating formed on the compressed core. The inner layer in contact with the compressed core consists essentially of a plasticized water insoluble pharmaceutically acceptable polymer. Chen et al. teach that cellulosic polymers may be combined with the water insoluble polymer to modify the permeability of the inner layer. The outer layer positioned over the inner layer is an immediate release coating. The outer layer consists essentially of an effective amount of a medicament and a water soluble polymer and is very soluble in water (see col. 4, lines 1-4).

The outer layer positioned over the inner layer is not a semipermeable membrane that maintains its physical and chemical integrity.

From the foregoing, it is clear that Chen et al. do not anticipate the invention recited in claim 46. Withdrawal of the rejection of claim 46 over Chen et al. is respectfully requested. Claims 48, 51, and 53-58, which depend from claim 46, are likewise patentable over Chen et al. Claim 60, which recites a method of delivering a therapeutic agent to the subject comprising administering the dosage form of claim 46, is also patentable in view of the foregoing arguments.

B. Claims 46, 48, 51-60 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bartoo et al. (U.S. Patent No. 4,743,248). Claim 52 has been cancelled. Accordingly, rejection of claim 52 is moot. Reconsideration of the rejection of claims 46, 48, 51, and 53-60 is respectfully requested.

Bartoo et al. teach an inner wall in contact with a formulation that always includes an enteric element, e.g., hydroxypropylmethylcellulose phthalate, which is sensitive to pH and only dissolves in high pH. Thus, the inner wall is activated by pH. In contrast, the first membrane recited in claim 46 consists essentially of a hydrophobic substance and a hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of the formulation. The first membrane does not contain an enteric element and is activated by hydrophobicity and the time to hydrate.

From the foregoing, Bartoo et al. do not disclose or teach a first membrane in contact with a formulation, the first membrane consisting essentially of a hydrophobic substance and a hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of the formulation, as recited in claim 46. Withdrawal of the rejection of claim 46 over Bartoo et al. is respectfully requested. Claims 48, 51, and 53-59, which depend from claim 46, are likewise patentable over Bartoo et al. Claim 60, which recites a method of delivering a therapeutic agent to the subject comprising administering the dosage form of claim 46, is also patentable in view of the foregoing arguments.

Conclusion

The rejected claims have been amended and/or shown to be allowable over the prior art. Applicants believe that this paper is fully responsive to each and every ground of rejection cited by the Examiner in the Office Action dated May 5, 2004, and respectfully request that a timely Notice of Allowance be issued in this case.

Please apply any charges or credits in connection with filing of this response to Deposit Account No. 50-3202 (Docket No. ARC 2762C1).

Respectfully submitted,

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